

Application Number 10/589,862
Response to the Office Action dated June 11, 2008

REMARKS

Claim 1 has been amended to remove the optionally added pigments; accordingly, claim 16, which includes the pigments but does not include the brand name of the pigments, has been added to differentiate this claim from claim 9 as supported by original claim 1.

Claim 11 has been amended to remove the optionally added pigments; accordingly, claim 17, which includes the pigments as ingredients of the composition, has been added as supported by original claim 11.

Claims 2-9 have been amended to remove the preferable ranges or the phrase "preferably" in these claims; claims 1 and 5-11 have been amended editorially.

Claims 12-15, which correspond to original claims 2, 4, 6, and 8, respectively, and include the respective preferable ranges of original claims 2, 4, 6, and 8, have been added.

Claims 2-8 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

Claims 2-8 have been amended to remove the preferable ranges or the phrase "preferably" and the preferable ranges in original claims 2, 4, 6, and 8, which are narrower than the stated limitations before the preferable range in these original claims, are included in newly added claims 12-15, respectively . Accordingly, this rejection is moot and should be withdrawn.

Claims 1, 2, and 4-11 have been rejected under 35 U.S.C. 102(b) as being anticipated by Foukes et al. (U.S. Patent No. 5,498,783). Applicants respectfully traverse this rejection.

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Foukes discloses a powder coating composition and use of that powder coating composition for panels such as automotive panels (see coln. 1, lines 19-24 and examples at coln. 10, lines 24-44) and further discloses that the powder coating composition includes 1-20% of a reactive acrylic copolymer (see coln. 2, lines 35-44). Foukes, however, fails to disclose use of methacrylate copolymer of Type C as claims 1 and 11 require. The methacrylate copolymer of Type C is a specific type of methacrylate copolymers, and there are other types of methacrylate such as Type A and Type B listed in the U.S. Pharmacopeia (USP) as materials that can be used for drugs (see MSDS of Types A, B, and C by USP attached hereto). In addition, in contrast to the reference, which discloses the range of the reactive acrylic copolymer between 1-20 wt% (see coln. 2, lines 35-44), claims 2 and 12 require the content of methacrylate copolymer of Type C between 20 and 90 wt% and between 40 and 70 wt%, respectively. According to the above, the dry powder compositions of claims 1 and 11 are distinguished from the powder coating composition of Foukes, and this rejection should be withdrawn.

Claims 1-11 have been rejected under 35 U.S.C. 102(b) as being anticipated by Mehra et al. (U.S. Patent No. 5,733,575). Applicants respectfully traverse this rejection.

Mehra discloses an enteric film coating dry powder composition that includes forming polymer such as PVAP-T, PVAP-J, HPMCP, HPMCAS, or CAP (see coln. 2, lines 12-20) and fails to disclose use of methacrylate copolymer of Type C as claims 1 and 11 require. In addition, Mehra discloses use of an alkalinizing agent such as bicarbonate, carbonate, phosphate, or hydroxide of sodium or potassium, magnesium carbonate, magnesium hydroxide, ammonium carbonate, ammonium bicarbonate, magnesium oxide, calcium hydroxide, or mixtures thereof (see coln. 3, lines 52-56). The alkalinizing agent is used to prevent coalescing or blockage of the spray lines and guns and reduce the tackiness of the coating (see coln. 4, lines 3-7). The polyacid forming polymer such as CAP (cellulose acetate phthalate) has low solubility in water, practically insoluble (no more than 5.0 %) in water (see page 892 "Description" and page 893 "Water" of Japanese Pharmacopeia attached hereto), and cannot provide sufficient dispersion in water for uniform coating. Therefore, an alkalinizing agent is used to

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neutralize the polyacid polymer and disperse the polymer in water, and additionally, to provide enteric drugs with long-term stability (see page 2, first and second paragraphs of summary of the invention section in the specification). The invention of claims 1 and 11 is directed to a composition or a method that does not use the alkalinizing agent. The composition and method of claims 1 and 11 can achieve the same properties such as uniform coating without formation of coagulum and long-term stability without using the alkalinizing agent (see page 2, summary of invention section - page 3, line 9 of the specification). It should be understood that pharmaceuticals including less non-active ingredients are better because even excipients that are approved for use in pharmaceuticals such as the alkalinizing agents in the reference may have some toxicity at high doses (see MSDS of sodium bicarbonate attached hereto) and possibly interact with an active ingredient or other excipients in the pharmaceutical, as well as the economic benefit of requiring fewer ingredients for manufacturing pharmaceuticals. Accordingly, claims 1 and 11 are distinguished from the reference.

Claims 1-11 have been rejected under 35 U.S.C. 102(b) as being anticipated by Lech et al. (U.S. Patent No.5,641,513). Applicants respectfully traverse this rejection.

Lech discloses use of coating polymer such as cellulose ethers, vinyls, glycols, and acrylics for coating pharmaceutical tablets (see coln. 4, lines 31-39). The reference, however, fails to disclose use of a methacrylate copolymer of Type C as claims 1 and 11 require. Accordingly, claims 1 and 11 are distinguished from Lech, and this rejection should be withdrawn.

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In view of the above, Applicants request reconsideration of the application in the form of a Notice of Allowance.



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